

**(Not to be Published)**

Human papillomavirus vaccine;  
Autonomic dysfunction;  
Hypersomnia;  
Decision dismissing petition;  
Vaccine Rule 21; RCFC 41.

<sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter “Vaccine Act” or “the Act”). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

November 23, 2015, and February 8, 2016, caused him to experience an adverse reaction, including idiopathic hypersomnia, prolonged general fatigue, and autonomic dysfunction. The case caption was amended in 2018 when A.M. turned 18, making Mr. Miller the Petitioner.

During the case's life, Petitioner filed medical records from various treating physicians and affidavits from witnesses in support of his claim. *See e.g.*, Ex. 4, filed on October 18, 2017 (ECF No. 6-4); Ex. 7, filed on October 18, 2017 (ECF No. 6-7); Ex. 8, filed on October 18, 2017 (ECF No. 6-8). Petitioner also submitted expert reports and supporting medical literature. *See e.g.*, Ex. 13, dated April 16, 2018, (ECF No. 15-1); Ex. 15-24, dated June 29, 2018, (ECF No. 19-1 – 19-10). The case was transferred to me on July 30, 2020, and after an initial review of the file I invited the parties to propose dates for an entitlement hearing. *See* September 8, 2020 Docket Entry Order.

On October 20, 2020, instead of proposing a hearing date, Petitioner filed what he styled a "Motion for a Decision Dismissing his Petition." ECF No. 52 ("Motion"). In it, Petitioner requests that I dismiss his claim prior to issuance of a full written decision, based on his expressed desire to opt out of the Program and "pursue a third party action in district court" against the manufacturer of the HPV vaccine. Motion at 2. He also represented that Respondent had no objection to the requested relief.

On November 3, 2020 (and despite Petitioner's prior representation that the dismissal request was unopposed), Respondent filed a brief in reaction to Petitioner's Motion. ECF No. 53 ("Response"). Respondent did not dispute his consent to the relief sought in the Motion, but nevertheless provided a detailed explanation of his assessment for why the case was appropriately dismissed. Response at 1. In particular, Respondent argued that Petitioner has not established that he has idiopathic hypersomnia ("IH"). *Id.* at 3. Further, assuming *arguendo* that Petitioner actually had IH, his claim would still fail because he could not provide scientifically reliable and preponderant evidence establishing his burden under the applicable standard. *Id.* at 5.

### **PETITIONER'S CLAIM**

Prior to evaluating the merits of Petitioner's motion, some brief consideration of the evidentiary support for this claim is required. On April 16, 2018, and December 13, 2018, Petitioner filed expert reports from Mitchell Miglis, M.D., who specializes in autonomic disorders. Ex. 13, 31. Dr. Miglis opined that Mr. Miller's HPV vaccinations likely caused him to develop IH. Ex. 13 at 16. Besides this expert support, Petitioner marshaled some other proof in support of the claim. Thus, Petitioner's treaters associated his increased need for sleep with the HPV vaccine because of the temporal relationship between the two. Ex. 7 at 20. They also noted that Petitioner's symptoms appeared to worsen after the administration of the second dose of the HPV vaccine. Ex. 4 at 1.

In reaction to Dr. Miglis’s opinion, Respondent filed an expert report from Kiran Maski, M.D., who challenged the determination that Petitioner has IH, or that IH could be caused by the HPV vaccine. *See* Report, filed as Ex. A (ECF No. 25). As Dr. Maski contended, objective sleep studies performed on Petitioner did not confirm a diagnosis of IH and, as a result, Petitioner could not establish that he has that condition. *See* Ex. A. Petitioner thereafter filed a supplemental report from Dr. Miglis on December 13, 2018, wherein he conceded that Petitioner’s diagnostic testing did not meet criteria for an IH diagnosis, but maintained that Petitioner still likely developed IH as a result of HPV vaccination. Ex. 31 at 1-2. Because Dr. Miglis proposed no other diagnosis, Respondent argues that Petitioner’s claim necessarily fails.

### ANALYSIS

The provisions under the Vaccine Rules for ending a case *before* a decision has been issued are largely inapplicable herein. Petitioner may no longer avail himself of Vaccine Rule 21(a)(1)(A), which governs voluntary dismissals before service of the Rule 4(c) Report, and Respondent has not stipulated to dismissal under Rule 21(a)(1)(B). In addition, even if the parties had so stipulated, Petitioner seeks entry of a judgment, whereas Vaccine Rule 21(a) would only result in an “order concluding proceedings.” Rule 21(a)(3).

Accordingly, the only remaining channel for the relief Petitioner requests is a “motion seeking dismissal”—an informal mechanism for ending cases that other petitioners have used, either because they have determined that the claim cannot succeed, or simply because they choose not to continue with the claim, but have reached that determination after the time to act under Rule 21 has passed. *See, e.g., Goldie v. Sec’y of Health & Human Servs.*, No. 18-1476V, 2019 WL 6045647, at \*1 (Fed. Cl. Spec. Mstr. Oct. 11, 2019). Generally, petitioners who wish to dismiss a case after filing of the Rule 4(c) Report usually include in their dismissal motion an acknowledgement that the claim cannot succeed. These words are missing from Petitioner’s Motion – on the contrary, he takes pains to emphasize that he does *not* believe the claim cannot be substantiated. Motion at 2. Petitioner does, however, acknowledge that any Decision dismissing the case at this point will not only be adverse to seeking relief in the Program in the future (based on this vaccination), but also may well include some comment on the evidence filed. *Id.* at 2-3.

Thus, although it is true that the present circumstances do not afford Petitioner a means of dismissal directly under the Vaccine Rules, dismissal of petitions can still occur at this point in the claims life. Indeed, the rules of the Court of Federal Claims (which are properly applied herein)<sup>3</sup>

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<sup>3</sup> The Vaccine Rules specifically stated that the Rules of the Court of Federal Claims “apply only to the extent they are consistent with the Vaccine Rules,” and otherwise empower special masters to “regulate the applicable practice” under the Vaccine rules “[i]n any matter not specifically addressed” therein. Vaccine Rule 1(b) and (c). Here, I find that permitting dismissal—in the form stated in this Decision—based on a rule of the Court of Federal Claims is fully consistent with the Vaccine Rules, given that language of Vaccine Rule 21 does not cover voluntary dismissal by court order, whereas RCFC 41 does cover voluntary dismissal by court order. Thus RCFC 41(a)(2) addresses a situation not contemplated by Vaccine Rule 21.

permit dismissal of claims at a petitioner/plaintiff's request and "on terms that the court considers proper." RCFC 41(a)(2). Accordingly, I find it is appropriate to grant Petitioner's Motion, even though it does not contain the customary acknowledgement that the claim cannot succeed in the Program. Expediency, judicial efficiency, and providing fairness to Vaccine Program claimants—values that constantly inform the work of special masters in deciding vaccine injury claims—all counsel in favor of allowing dismissal when requested by a petitioner. Dismissal of the case will obviate the need to write a lengthy decision, and cut off the prospect of future appeal as well (at least on matters not pertaining to attorney's fees), thus further preserving judicial resources.

However, and in accordance with RCFC 41(a)(2), this Decision shall include several express limitations in order to make it conform to the requirements of Section 12(d)(3) of the Act. In particular, I find that (as Petitioner has anticipated) Petitioner did *not* establish his claim by a preponderance of the evidence. Petitioner's causation theory had some surface plausibility, but ultimately was unreliable and not supported by sufficient scientific/medical evidence.

As acknowledged by Petitioner's expert, Dr. Miglis, there are no known published case series of IH caused by the administration of the HPV vaccine. Ex. 13 at 16. He instead relied upon VAERS (Vaccine Adverse Event Reporting System) data to conclude that there is a causal connection between HPV vaccine and IH (*Id.* at 8), even though this type of support is not sufficient to meet the level of preponderance required in the Program. Dr. Miglis also conceded that the cause of IH is unknown. *Id.* at 5. He could, in the end, only speculate that because some cases have been reported after viral illness, this suggests a possible immune etiology. *Id.* But speculation, supported by no more than temporal association, does not satisfy the preponderant test applied to Program claims.<sup>4</sup> In addition, and as Respondent has observed, Petitioner's purported IH is not preponderantly supported by the record. Lack of proof of an alleged injury is a well-recognized independent basis for dismissal of a claim. *Broekelschen v. Sec. of Health & Human Servs.*, No. 07-137V, 2009 WL 440624 (Fed. Cl. Spec. Mstr. Feb. 4, 2009), *aff'd*, 618 F.3d 1339 (Fed. Cl. 2010).

As a result, after careful review of the record, I find that Petitioner could not preponderantly establish entitlement to a damages award. Moreover, this dismissal is *with prejudice*.<sup>5</sup> And I note

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<sup>4</sup> I also note that Dr. Miglis testified for a different claimant in a Program case also alleging that the HPV vaccine caused injury. *See, e.g., Otto v. Sec. of Health & Human Servs.*, No. 16-1144, 2020 WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020). That case went to hearing, and I had the opportunity to see Dr. Miglis and listen to his testimony. Although I found him a qualified expert overall, I was not persuaded by his arguments about the capacity of the HPV vaccine to cause injury in that case – and from review of the written reports, I can state that it is highly unlikely I would have reached a different determination *in this case*, even though the injury is different, given the overall lack of reliable scientific/medical evidence associating the HPV vaccine to sleep-related disorders.

<sup>5</sup> Rule 41(a)(2) gives the Court discretion as to whether a dismissal should be with or without prejudice. *See Giesecke & Devrient GmbH v. United States*, 146 Fed. Cl. 631, 641 (Fed. Cl. 2020) ("[u]nder Rule 41(a)(2), a voluntary dismissal by court order is 'without prejudice' unless the court finds that the defendant will suffer legal prejudice,

that Respondent has not conceded that the claim possessed reasonable basis, and therefore may challenge any final fees request in this matter on that ground (although I also note that I was prepared to permit this matter to be tried, reflecting my admittedly-tentative conclusion after the case's transfer that the novelty of injury alleged raised a kind of claim somewhat different than the many other HPV claims I have adjudicated—a factor that would favor Petitioner in any fees request that is challenged on reasonable basis grounds).

## CONCLUSION

Under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on his claims alone. In this case, there is insufficient evidence in the record for Petitioner to meet his burden of proof, and insufficient reliable scientific proof offered in support of his causation theory. Therefore, Petitioner's claim cannot succeed and must be dismissed. Section 11(c)(1)(A).

Accordingly, Petitioner's Motion for a Decision Dismissing the Case is hereby GRANTED, and the Petition is dismissed **with prejudice**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.<sup>6</sup>

**IT IS SO ORDERED.**

s/ Brian H. Corcoran  
Brian H. Corcoran  
Chief Special Master

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such as when a plaintiff “does not seek dismissal until a late stage” in the litigation”). There are three factors to consider on whether a dismissal should be with or without prejudice: “(i) the burden on the defendant if the case were to be dismissed without prejudice; (ii) the progress of the litigation; and (iii) the diligence and good faith of the plaintiff.” *Klamath Irrigation District v. United States*, 116 Fed. Cl. 117, 119 (Fed. Cl. 2014).

Here, the late stage of the litigation—a case pending for three years, featuring multiple experts and reports, full fact discovery, and ample briefing, weighs in favor of dismissal with prejudice.

<sup>6</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.